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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/019,506	05/10/2002	Robert Bartlett Elliott	GL216721-003	8690

466 7590 07/14/2004

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 07/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/019,506	ELLIOTT ET AL.	
	Examiner	Art Unit	
	Randall Winston	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 May 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *15-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1:

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 15-27, drawn to a dietary supplement comprising a beta-casein content which excludes beta-casein A1 and beta-casein B in addition to an effective amount of at least one compound selected from the group consisting of betaine, cobalamin, folic acid and pyridoxine and a pharmaceutically acceptable analogue and/or drawn to a method for reducing the incidence in a population comprising supplying the population a dietary supplement including beta-casein A2 but substantially no beta-casein A1 or beta-casein B etc.

Group II. Claims 28-32, drawn to a dietary supplement comprising an immunomodulating component which is beta-casomorphin 9 or an analogue or precursor thereof and a fortify component an/or drawn to a method of reducing the incidence in a population comprising supplying to the population a dietary supplement as claimed in claim 28.

Group III. Claim 33, drawn to a use of milk or milk product containing beta-casomorphin-9 or an analogue or precursor thereof, in the manufacture of a dietary supplement as claimed in claim 28 for treating or preventing a disease.

Group IV. Claim 34-36, drawn to a dietary supplement which substantially excludes beta-casein A1 and beta-casein B, which contains beta-casomorphin-9 or an analogue or precursor thereof.

The inventions listed as Groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of each composition and each method: Group I is a dietary supplement comprising a beta-casein content which excludes beta-casein A1 and beta-casein B in addition to an effective amount of at least one compound selected from the group consisting of betaine, cobalamin, folic acid and pyridoxine and a pharmaceutically acceptable analogue and/or is a method for reducing the incidence in a population comprising supplying the population a dietary supplement including beta-casein A2 but substantially no beta-casein A1 or beta-casein B etc and the special technical feature of Group II is a dietary supplement comprising an immunomodulating component which is beta-casomorphin 9 or an analogue or precursor thereof and a fortify component and/or is a method of reducing the incidence in a population comprising supplying to the population a dietary supplement as claimed in claim 28 and the special technical feature of Group III is a use of milk or milk product containing beta-casomorphin-9 or an analogue or precursor thereof, in the manufacture of a dietary supplement as claimed in

claim 28 for treating or preventing a disease and the special technical feature of Group IV is a dietary supplement which substantially excludes beta-casein A1 and beta-casein B, which contains beta-casomorphin-9 or an analogue or precursor thereof.

Thus, Group I, II and III are unrelated methods because the methods' preamble and/or objectives are different and/or Group I, II, III utilize a different product to reach its preamble's purpose (i.e. Group I's method utilizes a different product from Group II's method product to reach its preamble's purpose and/or Group I preamble's purpose is different from GroupIII's preamble's purpose). Moreover, the claimed composition such as Group I, II and IV are unrelated compositions because each composition comprise of different active ingredients.

For the reasons above, the inventions of Groups I-IV do not share a special technique This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: Group I, claim 27, Group II, claim 32 and Group III claim 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

For Group I, claim 27, for Group II, claim 32 and for Group III, claim 33 the claimed species are:

a) type I diabetes b) type II diabetes c) cardiovascular disease d) cerebrovascular disease e) peripheral vascular disease f) neural tube defects and g) degeneration of blood vessel walls.

Applicant is required to elect under PCT Rule 13.2, a single disclosed species for Group I, II and III from the list of a-g above for prosecution on the merits to which the claims shall be restricted I no generic claims is finally held to be allowable.

Accordingly, the search for each of the above inventions is not co-extensive particularly with regard to the literature. Further, the reference which would anticipate the invention of one group would not necessarily anticipate or even make obvious the other group.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PATRICIA LEITH
PRIMARY EXAMINER